

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Niall Galloway, M.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Defendant's Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. filed by Boston Scientific Corporation ("BSC"). [ECF No. 4818]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, BSC's Motion is **GRANTED in part, DENIED in part, and DENIED as moot in part.**

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the BSC MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v.*

Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We

agree with the Solicitor General that “[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Galloway is an Associate Professor of Surgery (Urology) at the Emory University School of Medicine in Atlanta, Georgia. His practice consists largely of handling complications stemming from synthetic mesh placement in the vagina for POP and SUI.

A. BSC’s Knowledge or State of Mind

First, BSC argues that I should preclude Dr. Galloway from testifying as to BSC’s knowledge or state of mind. I agree; experts may not testify about what other parties did or did not know. However, to the extent BSC seeks to exclude Dr. Galloway’s testimony about factual issues or the knowledge of the medical community

in general, I disagree. Expert witnesses may properly offer opinions on these topics. Therefore, BSC's Motion is **GRANTED** to the extent that it seeks to exclude evidence regarding BSC's knowledge or intent.

B. Material Safety Data Sheet ("MSDS")

Second, BSC argues that two of Dr. Galloway's opinions related to the MSDS for polypropylene resin are irrelevant. Specifically, BSC seeks to exclude two of Dr. Galloway's opinions on this topic:

- (1) I have seen no evidence that Boston Scientific disclosed this information to doctors and patients, nor did Boston Scientific seek further information, or do appropriate testing to determine the validity of these warnings. This is information that doctors and patients are entitled to know and need to know in order to make informed decisions regarding treatment options. Without complete and accurate information, informed consent is not possible.
- (2) In my opinion, placing a material that degrades, releases potentially toxic chemicals, creates a chronic inflammatory response, and was advised against by the manufacturers of the raw component represents a serious flaw in the design of Boston Scientific's transvaginal mesh devices.

Galloway Report 9–10. With regard to Dr. Galloway's first opinion, his discussion of BSC's corporate conduct will not be helpful to the jury and is thus **EXCLUDED**. BSC's Motion regarding this opinion is **GRANTED**.

With regard to the second opinion, BSC argues that it is irrelevant "because an MSDS is aimed at communicating workplace chemical hazards to employers and employees, not to doctors or end-users of medical products." I disagree. Throughout these MDLs, the court has consistently admitted evidence related to the MSDS (from

properly qualified experts) as relevant to the issue of the defendants' negligence. Accordingly, BSC's Motion regarding Dr. Galloway's second opinion is **DENIED**.

C. Adequacy of Warnings

Third, BSC seeks to exclude Dr. Galloway's opinion that alphabetizing the risks in the Directions for Use trivializes certain adverse events. Although Dr. Galloway states that listing complications in order of importance is "convention," he fails to provide any basis for this statement, and the court has no way of assessing its reliability. Accordingly, BSC's motion with regard to the alphabetical listing of complications is **GRANTED**, and this opinion is **EXCLUDED**.

D. Trocars

Fourth, BSC contends that Dr. Galloway's opinions on trocars, the instrument used to implant certain transvaginal mesh devices, should be excluded because the implantation of the Uphold does not require the use of a trocar. In response, the plaintiffs concede that Dr. Galloway's opinions related to the use of trocars will only be offered if the case involves the use of a trocar. Accordingly, BSC's motion with regard to trocars is **DENIED as moot**.

E. Legal Conclusions

Finally, BSC contends that Dr. Galloway seeks to offer testimony constituting various legal opinions. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th

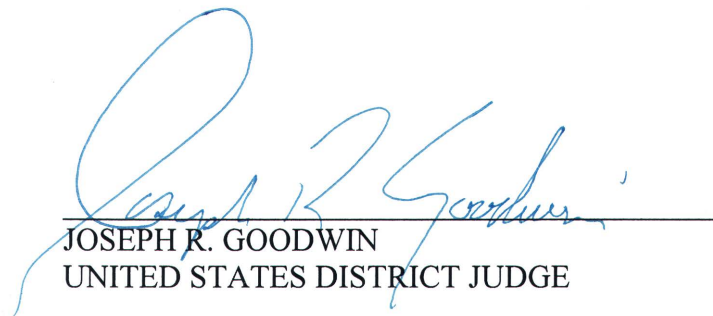
Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008). Thus, to the extent that Dr. Galloway’s opinions constitute legal conclusions, those opinions are **EXCLUDED**. BSC’s Motion is **GRANTED** on this point.

IV. Conclusion

To summarize, BSC’s *Daubert* Motion concerning Dr. Galloway [ECF No. 4818] is **GRANTED in part, DENIED in part, and DENIED as moot in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-00047	Long v. Boston Scientific Corporation
2:17-cv-00049	Parker et al v. Boston Scientific Corporation
2:17-cv-00294	Grigg v. Boston Scientific Corporation
2:17-cv-00304	Martinez v. Boston Scientific Corporation
2:17-cv-00307	Michael v. Boston Scientific Corporation
2:17-cv-00314	Newton v. Boston Scientific Corporation
2:17-cv-00315	Norris v. Boston Scientific Corporation
2:17-cv-00317	Norris v. Boston Scientific Corporation
2:17-cv-00318	Osborn v. Boston Scientific Corporation
2:17-cv-00325	Pick v. Boston Scientific Corporation
2:17-cv-00528	Sustaita v. Boston Scientific Corporation
2:17-cv-00534	Notestine v. Boston Scientific Corporation
2:17-cv-00536	Sutiff v. Boston Scientific Corporation
2:17-cv-00568	Mahnke v. Boston Scientific Corporation
2:17-cv-00701	Babcock v. Boston Scientific Corporation
2:17-cv-01074	Dembski v. Boston Scientific Corporation
2:17-cv-01098	Zeiter v. Boston Scientific Corporation

2:17-cv-01109	Herbert et al v. Boston Scientific Corporation
2:17-cv-01241	Tigner v. Boston Scientific Corporation
2:17-cv-01242	Evans v. Boston Scientific Corporation
2:17-cv-01243	Brown v. Boston Scientific Corporation
2:17-cv-01837	Allen v. Boston Scientific Corporation
2:17-cv-01845	Shiflet v. Boston Scientific Corporation
2:17-cv-01862	Faso et al v. Boston Scientific Corporation
2:17-cv-01900	Hauff et al v. Boston Scientific Corporation
2:17-cv-01925	Skalniak et al v. Boston Scientific Corporation
2:17-cv-01932	Peach v. Boston Scientific Corporation
2:17-cv-01938	Schroder v. Boston Scientific Corporation
2:17-cv-01939	Price v. Boston Scientific Corporation
2:17-cv-01940	Conley v. Boston Scientific Corporation
2:17-cv-01959	Lowrie v. Boston Scientific Corporation
2:17-cv-01977	Hardwick v. Boston Scientific Corporation
2:17-cv-01979	Dunford et al v. Boston Scientific Corporation
2:17-cv-01990	Hill-Sober et al v. Boston Scientific Corporation
2:17-cv-01996	Benson v. Boston Scientific Corporation

2:17-cv-02093	Pamensky Murray v. Boston Scientific Corporation
2:17-cv-02106	Wilson v. Boston Scientific Corporation
2:17-cv-02107	Ross v. Boston Scientific Corporation
2:17-cv-02110	Clark v. Boston Scientific Corporation
2:17-cv-02111	Busby v. Boston Scientific Corporation
2:17-cv-02202	Atwood v. Boston Scientific Corporation
2:17-cv-02243	Alvarado v. Boston Scientific Corporation
2:17-cv-02244	Speed v. Boston Scientific Corporation
2:17-cv-02416	Palmer v. Boston Scientific Corporation
2:17-cv-02417	Masterson v. Boston Scientific Corporation
2:17-cv-02443	Allex v. Boston Scientific Corporation
2:17-cv-02446	Blalock v. Boston Scientific Corporation
2:17-cv-02447	Casale v. Boston Scientific Corporation
2:17-cv-02448	Clark v. Boston Scientific Corporation
2:17-cv-02449	Cole v. Boston Scientific Corporation
2:17-cv-02450	Wallace v. Boston Scientific Corporation
2:17-cv-02459	Mallory v. Boston Scientific Corporation
2:17-cv-02461	Martin v. Boston Scientific Corporation

2:17-cv-02462	McSween v. Boston Scientific Corporation
2:17-cv-02467	Melrose v. Boston Scientific Corporation
2:17-cv-02470	Porter v. Boston Scientific Corporation
2:17-cv-02471	McFalls v. Boston Scientific Corporation
2:17-cv-02477	Pouncy v. Boston Scientific Corporation
2:17-cv-02481	Shepard v. Boston Scientific Corporation
2:17-cv-02483	Smith v. Boston Scientific Corporation
2:17-cv-02486	Daniell v. Boston Scientific Corporation
2:17-cv-02505	Cutlip v. Boston Scientific Corporation
2:17-cv-02508	Jeter v. Boston Scientific Corporation
2:17-cv-02524	Murphy v. Boston Scientific Corporation
2:17-cv-02525	Price v. Boston Scientific Corporation
2:17-cv-02527	Roark v. Boston Scientific Corporation
2:17-cv-02528	Saldivar v. Boston Scientific Corporation
2:17-cv-02531	Smith v. Boston Scientific Corporation
2:17-cv-02533	Southwood v. Boston Scientific Corporation
2:17-cv-02551	Solomon v. Boston Scientific Corporation
2:17-cv-02553	Spencer v. Boston Scientific Corporation

2:17-cv-02554	Stark v. Boston Scientific Corporation
2:17-cv-02562	Vincent v. Boston Scientific Corporation
2:17-cv-02566	Walker v. Boston Scientific Corporation
2:17-cv-02568	Welsh v. Boston Scientific Corporation
2:17-cv-02571	Wittenborn v. Boston Scientific Corporation
2:17-cv-02588	Adams v. Boston Scientific Corporation
2:17-cv-02589	Barnett v. Boston Scientific Corporation
2:17-cv-02590	Childress v. Boston Scientific Corporation
2:17-cv-02592	Dickeson v. Boston Scientific Corporation
2:17-cv-02596	McFolling v. Boston Scientific Corporation
2:17-cv-02597	Morgan v. Boston Scientific Corporation
2:17-cv-02598	Reid v. Boston Scientific Corporation
2:17-cv-02599	Reyes v. Boston Scientific Corporation
2:17-cv-02600	Rinaldi v. Boston Scientific Corporation
2:17-cv-02601	Woodard v. Boston Scientific Corporation
2:17-cv-02633	Pierson et al v. Boston Scientific Corporation
2:17-cv-02636	Walseth v. Boston Scientific Corporation
2:17-cv-02638	Buttke v. Boston Scientific Corporation

2:17-cv-02641	Harrison-Hood v. Boston Scientific Corporation
2:17-cv-02646	Gottfreid v. Boston Scientific Corporation
2:17-cv-02730	Black v. Boston Scientific Corporation
2:17-cv-02734	Henjum v. Boston Scientific Corporation
2:17-cv-02738	Martin v. Boston Scientific Corporation
2:17-cv-02739	Martinez v. Boston Scientific Corporation
2:17-cv-02742	Morales v. Boston Scientific Corporation
2:17-cv-02745	Shaw v. Boston Scientific Corporation
2:17-cv-02787	Stapf v. Boston Scientific Corporation